February 11, 2002

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane (Room 1061)
Rockville, MD 20852

Re: Comments on "Draft FDA Guidance for Industry; Electronic Records; Electronic Signatures, Glossary of Terms"; Docket No. 00D-1543

Dear Sir/Madam:

Although this comment is being submitted after the close of the published comment period, I hope you will consider its merit as you deliberate changes to the draft guidance referenced above.

We recommend that a definition be included for the term “hybrid system”. With respect to Part 11, this term is used more frequently than some of the other terms found in the draft glossary, and it is a source of confusion due to the lack of a standard definition. A suggested two-part definition follows:

(1) An environment consisting of both electronic and paper-based records, frequently characterized by handwritten signatures captured electronically or on paper. (2) An environment consisting solely of electronic records and handwritten signatures captured electronically.

Thank you for considering this suggestion.

Sincerely,
SEC ASSOCIATES, INC.

John C. McKenney, Sr.
President